

RECEIVED
CENTRAL MAIL ROOM

MAR 11 2005

Attorney's Docket No.: 08919-016003
Client's Ref. No.: 13A-870916 (CON)

U.S. PATENT AND TRADEMARK OFFICE
OFFICIAL COMMUNICATION FACSIMILE:
FAX NO: (703) 872-9306

Number of pages including this page 5

Applicant : Chen-Kun James Shen Art Unit : 1636
Serial No. : 09/977,432 Examiner : Sumesh Kaushal
Filed : October 15, 2001

Title : HS-40 ENHANCER-CONTAINING VECTOR

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attached to this facsimile communication cover sheet is **STATEMENT OF
SUBSTANCE OF INTERVIEW OF FEBRUARY 8, 2005**, faxed this 11th day of March,
2005, to the United States Patent and Trademark Office.

Respectfully submitted,

Jiauming Hao
Reg. No. 54,694

PTO Customer No. 26161
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Fax: (617) 542-8906

21044925.doc

NOTE: This facsimile is intended for the addressee only and may contain privileged or confidential information. If you have received this facsimile in error, please immediately call us collect at (617) 542-5070 to arrange for its return. Thank you.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Chen-Kun James Shen Art Unit : 1636
Serial No. : 09/977,432 Examiner : Kaushal, Sumesh
Filed : October 15, 2001
Title : HS-40 ENHANCER-CONTAINING VECTOR

MAIL STOP AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF SUBSTANCE OF INTERVIEW OF FEBRUARY 8, 2005

Applicants would like to thank Examiners Remy Yucel and David Guzo for granting the telephone interview on February 8, 2005, regarding this application.

During the interview, Applicants' counsels, Y. Rocky Tsao (Reg. No. 34,058) and Jianming Hao (Reg. No. 54,694) discussed independent claim 33. This claim, rejected for obviousness, is drawn to a retroviral expression vector containing a mutant enhance element (SEQ ID NO: 1). More specifically, Applicants' counsel reiterated unexpected advantages exhibited by the claimed vector, which was previously presented in a declaration by the inventor. A letter sent to Examiner Yucel before the interview summarizes the unexpected advantages and related issues discussed in the interview. A copy of this letter is attached hereto as "Exhibit A".

The Examiners countered that the declaration noted above did not provide details of the retroviral vectors and transgenic method exemplified therein, and therefore declined to consider the declaration. Applicants' counsel proposed submitting a substitute declaration to include the alleged missing details. The Examiners agreed.

CERTIFICATE OF TRANSMISSION BY FACSIMILE

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date indicated below.

March 11, 2005

Date of Transmission

Signature

Deborah R. Nart

Typed or Printed Name of Person Signing Certificate

MAR 11 2005 9:57AM

(3) FISH & RICHARDSON 6175428906

NO. 8140 P. 3

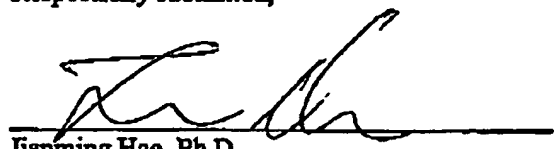
Applicant : Chen-Kun James Shen
Serial No. : 09/977,432
Filed : October 15, 2001
Page : 2 of 2

Attorney's Docket No.: 08919-016003 / 13A-870916
(CON)

Please apply any charges to deposit account 06-1050.

Respectfully submitted,

Date: 3-11-2005


Jianming Hao, Ph.D.
Reg. No. 54,694

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

21043033.doc

FISH & RICHARDSON P.C.

Frederick P. Fish
1859-1930

W.K. Richardson
1859-1991

VIA FACSIMILE

February 8, 2005

Examiner Yucel Irem
U.S. Patent & Trademark Office
Commissioner for Patents
Washington, D.C. 20231

Re: HS-40 ENHANCER-CONTAINING VECTOR
Appl. No.: 09/977,432
Our Ref.: 08919-016003

Dear Examiner Irem:

Thank you for granting a telephone interview, scheduled for 2:30 pm, Feb. 8, 2005 to resolve an issue raised in the final office action. As I know you are busy, I will limit this discussion to claim 33. Hopefully, the summary below will facilitate your understanding of this issue.

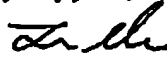
Claim 33, rejected for obviousness, covers a viral expression vector that contains, among others, a mutant element of the HS-40 enhancer, i.e., SEQ ID NO:1 or its complement. In the response to the final office action and two subsequent supplemental responses, we presented unexpected advantages of the claimed vector as compared with that of (1) a vector containing wild type counterpart of SEQ ID NO: 1 ("control vector") or (2) a vector described in a non-prior art reference Lung et al., which contains wild type HS-40 enhancer. The table appended to this letter shows the expression patterns by these three vectors.

In the advisory action dated January 27, 2004, Examiner Kaushal countered that the expression pattern of the claimed vector in transgenic mice is not unexpected as the Lung vector "is capable of providing high level of gene expression in [cancer cell lines]."

According to MPEP 716.02(a), "[e]vidence showing that the claimed [vector] was more effective than the closest prior art [vector in driving expression of a transgene in transgenic mice] was sufficient to overcome the rejection under 35 U.S.C. 103, even though ... the claimed [vector] was an average performer on [driving expression of a gene in cancer cell lines]." Also, note that there was a long felt but unsolved need for a vector having the above-mentioned unexpected advantages. See, e.g., the Specification, the paragraph bridging pages 4 and 5. Indeed, the Lung's failure to solve the problem supports this unexpectedness. The unexpected expression pattern by the claimed vector is sufficient to overcome the obviousness rejection.

We look forward to discussing with you the above issue at the interview.

Very truly yours,


Jianming Jimmy Hao, Ph.D.
Reg. No. 54,694

325 Franklin Street
Boston, Massachusetts
02110-2804

Telephone
617 542-5070

Facsimile
617 542-8906

Web Site
www.fr.com

ADAM
BOSTON
DALLAS
DELAWARE
NEW YORK
SAN DIEGO
SILICON VALLEY
TWIN CITIES
WASHINGTON, DC

FISH & RICHARDSON P.C.

Examiner Yucel Irem

February 8, 2005

Page 2

Table. In vivo and in vitro expression patterns by three vectors at issue

	A vector of claim 33	Control vector	Lung vector
In vivo expression pattern of a transgene in mice	1. Developmental stage-independent: Expressed in embryo stage and continued to express in adulthood. 2. Position-independent.	1. Developmental stage-dependent: Expressed in embryo stage but dropped significantly in the adult. 2. Position-dependent.	1. Failed to drive expression of a gene. 2. N/A
In vitro expression in cancer cell lines	Yes.	Yes.	Yes.

21024111.doc